EXPERT TESTIMONY REPORT

Hamilton versus Elemental Prism d/b/a Herb Stomp

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DOCUMENTS PROVIDED BY TORGER OAAS AND REVIEWED TO DEVELOP EXPERT TESTIMONY:

Postmortem Examination Report for Stephen Hamilton

Defendant's Answer to Plaintiff's Complaint

Deposition of Stephen Hamilton in Hamilton vs MHNet (Medical History)

Deposition of Jeffrey Quackenbush in Hamilton vs MHNet

Treatment Records from Rocky Mountain Treatment Center

Photos of Kratom shipped to Stephen Hamilton by Elemental Prism, d/b/a Herb Stomp

Internet Information on Herb Stomp

Affidavits of Stephanie Cataraha and Cody Klewin filed in this case

Photos of Infected Wounds

PREVIOUS EXPERT WITNESS TESTIMONY:

Medical Malpractice Case, Sage vs Clayton, 2018 – Current. Expert Witness Testimony in Addiction Medicine on behalf of defendant

Indiana Wrongful Death Case, 2016 – Contract Completed. On retainer as an expert witness in Addiction Medicine on behalf of the Plaintiff.

U.S. vs Mayfield, Expert Witness Testimony in Addition Medicine sought by USDOJ, 2016 – Contract Completed.

EXPERT WITNESS TESTIMONY FEES:

Flat Rate of $250/Hour for Case Research, Preparation of Expert Witness Report, and Expert Witness Testimony

Reimbursement of any travel expenses as appropriate and agreed to with Torger Oaas.

SUMMARY OF EXPERT TESTIMONY:

1) The facts of this case will show that despite stating on their website that the product (Kratom) is "Not Intended for Human Consumption," the seller was aware, or at least any reasonable seller would have been aware, that the sale of Kratom (in any of its forms) was being utilized by the purchaser for human consumption, and that by stating that the product is "not for human consumption," the seller was only trying to avoid litigation if an individual (such as Mr. Hamilton) were to have an adverse reaction from ingestion. The facts will show that the American Kratom Association, the leading advocacy group lobbying to maintain the legality of Kratom for personal use in the United States clearly intends that Kratom be used for "human consumption." The facts of the case will show that there is no rationale for an individual to purchase Kratom (i.e. it has no other value) except to be utilized for human consumption. The facts will show that individuals who use Kratom for various indications are aware that if Kratom were to have a label stating that it is "not for human consumption" such a label is applied to circumvent any potential litigation that could ensue thus making the label meaningless and ineffective. [1] In their written defense statement, it is already admitted by the seller that they were aware that others were purchasing Kratom for human consumption, (Page 2, Second Defense, Number 5) and yet, the facts of the case demonstrate that the seller continued to sell the product without additional labeling indicating potential side effects, adverse toxic effects, or drug-to-drug interactions associated with Kratom if ingested. The facts will also demonstrate that the American Kratom Association, again the leading advocacy and lobbying body for the continued availability of Kratom in the United States, has developed guidelines for the production, distribution, and sale of Kratom that clearly demonstrate the intent that it be sold for Human Consumption. Because of its psychoactive properties and potential for addiction, Kratom in the United States has become a 1.3 Billion Dollar Industry precisely because of such "human consumption." The facts will also demonstrate that the product purchased by Mr. Hamilton had no label on the package indicating that it was "Not Intended for Human Consumption," nor did it's label advise the individual of potential risks associated with use of Kratom, a fact which negates the attempt to use the law as a defense because the requirement is that the product itself be labeled (See photograph of product). In other words, the seller's attempt to mitigate litigation by stating on its website that Kratom, a product the seller is very well aware is being used solely for human consumption, as "not for human consumption," is not reasonably protected by Montana statute as stated in the seller's defense (Page 3, Third Defense).

2) The facts of this case will demonstrate that Kratom is not approved for use for ANY medical condition in the United States of America [2] and that it is associated with certain known risks and adverse side effects. It will be demonstrated that the primary psychoactive chemical components of Kratom (a botanical) are mitragynine and 7-Hydroxy Mitragynine. [2] Mitragynine is known to possess partial Mu-Opioid agonist activity and Kappa receptor antagonist activity similar to the FDA-Approved pharmaceutical drug, buprenorphine (marketed by various names and formulations and most commonly known as Suboxone® by the lay press). Buprenorphine has partial Mu-Opioid agonist activity and Kappa antagonist activity like Mitragynine. Unlike Buprenorphine, however, mitragynine may also possesses Delta Opioid Receptor agonist activity, and mild stimulant properties whose biochemical nature has not been clearly delineated (though likely on par with caffeine given the botanical relationship of Kratom to the Coffee plant). 7-Hydroxy Mitragynine, which tends to be present in lower concentrations than mitragynine in Kratom (approximately 2%), however, is a full Mu Opioid Receptor agonist with Kappa Receptor activity that has been shown to be 13 times more potent than morphine and 46 times more

potent than mitragynine. 7-hydroxy Mitragynine is now thought to be the primary alkaloid contributing to the pain-relieving properties of Kratom. [3] Given that 7-hydroxy mitragynine is a potent full mu opioid receptor agonist, unlike mitragynine, at higher doses, respiratory depression is likely to be of much greater concern than with mitragynine.

3) The facts will show that Kratom is most likely safe for consumption at "usual" doses of administration AND when not used in combination with other sedative/hypnotic/anxiolytic substances (including, but not limited to benzodiazepines, meprobamate, barbiturates, other opioid substances, gabapentin, or pregabalin), but can contribute to fatalities in combination with one (or more) of these agents or when taken in an amount greater than the "usual" dose. In other words, while Kratom may not possess toxicity on par with other pure Mu-opioid receptor agonists (such as heroin, oxycodone, morphine, etc.), it does appear to possess toxicity on par with that of the pharmaceutical agent buprenorphine (a partial mu-opioid agonist that has also been linked to numerous deaths at higher doses or in combination with other sedative/hypnotic/anxiolytic agents). The FDA recently published a computer modelling study that demonstrates what laboratory studies have already shown, that the active chemicals in Kratom (Mitragynine and 7-hydroxy mitragynine) function as mu-opioid receptor agonists (the Opioid receptor involved in addiction to heroin and other opioids), which is why individuals have touted the benefits of Kratom to prevent opioid withdrawal and assist with cravings. [4] The facts will also show that at high doses, Kratom (and more specifically its active components mitragynine and 7-hydroxy mitragynine) have been shown to increase the risk of a fatal heart arrhythmia through prolongation of the QT-Interval known as Torsade's De Pointe (a similar effect that is seen with methadone and which is possible with all opioid analgesics at high enough doses). [5] The facts will show that the Centers for Disease Control (CDC) has published reports that demonstrate such morbidity and mortality associated with use of Kratom that was well known prior to initiation of sales of Kratom to Mr. Hamilton. [6] The facts will also show that Kratom has been associated with at least 44 deaths in the United States (all in combination with another sedative/hypnotic/anxiolytic agent, alcohol, or another opioid). [4]

4) The facts will show that as a result of the increasing number of calls to poison control and the potential for morbidity and mortality associated with inappropriate labeling and use of Kratom, the Food and Drug Administration (FDA) attempted to ban the substance in 2016 by using its emergency powers to change the Federal Drug Enforcement Administration (DEA) schedule of Kratom to a Schedule 1 (illegal) Controlled Substance. [7] The DEA's attempt failed due to the strength of the grass roots advocacy efforts of the American Kratom Association, multiple scientists who believe that the constituents of Kratom may provide a new pharmaceutical for management of pain and opioid use disorder, and individual proponents of Kratom use which resulted in a Bipartisan coalition in Congress writing a letter to the FDA to postpone its action and to obtain additional information, clinical studies, and to hold a public listening session. The FDA has yet to provide a final ruling on the status of Kratom. The facts will show, however, that several States and municipalities have banned the production, distribution, sale, and/or consumption of Kratom within their borders because of concerns regarding the safety profile of Kratom including Alabama, Arkansas, Indiana, Rhode Island, Vermont, Wisconsin, and Washington, D.C. Kratom is also banned in numerous municipalities including Sarasota County in Florida, San Diego in California, and Jerseyville in Illinois. Numerous states also have pending legislation to ban Kratom including Illinois, Mississippi, New York, New Jersey, and West Virginia. In addition, Kratom has been banned for safety concerns in the following countries: Australia, Denmark, Finland, Israel,

Lithuania, Malaysia, Myanmar, Poland, Romania, South Korea, Sweden, Thailand, and the United Kingdom. [8,9]

5) The facts will show that Mr. Hamilton suffered from a severe opioid use disorder, an alcohol use disorder, Type 1 Diabetes Mellitus, polysubstance use, and Major Depression but will also demonstrate that he was very involved in treatment prior to his death and invested in his treatment for addiction. At the time of his death, there was significant evidence to suggest that he was trying very hard to maintain sobriety and that he resorted to Kratom in an attempt to do so (likely based on the anecdotal reports on multiple forums that tout Kratom as a "non-opioid" treatment option for pain control) as an alternative to opioid analgesics for pain control. As noted previously, there is no scientific basis for these claims at this time, though the pharmaceutical properties of the active components of Kratom provide some biochemical rationale for its potential to relieve pain given its opioid properties. Unfortunately, because Kratom (the botanical) and its chemical components (mitragynine and 7-hydroxy mitragynine) have not yet been adequately studied for any indication and because Kratom has been shown to interact with other pharmaceuticals and illicit substances to increase the risk of mortality, knowing that Kratom is ONLY purchased for human consumption, it is reasonable to expect that had the seller appropriately labeled the product (as noted previously), Mr. Hamilton would have, at minimum, discussed its use with his physician or medical provider or avoided using the product.

6) The facts of this case will show that Mr. Hamilton's use of Kratom significantly contributed, if not actually caused, his death. The facts will show that Mr. Hamilton's toxicology report after death demonstrated a mitragynine level (the primary psychoactive component of Kratom) that was significantly higher (2500 ng/ml) than levels reported in other cases where Kratom was considered contributory to the cause of death (20-600 ng/ml). [10] The facts will also demonstrate that the product (Kratom) as sold by the seller was not appropriately labeled to warn the consumer that there might be a potential drug-to-drug interaction between Kratom and other prescribed pharmaceuticals (including gabapentin which the patient was prescribed and taking as directed) or with underlying medical conditions (such as the patient's Type 1 Diabetes Mellitus). Given the seller's attempts to decrease the risk of litigation by stating on their website that the product is "not for human consumption" despite it clearly being sold for precisely that reason (as noted in #1 above), the seller did not bother to provide consumers with adequate warnings regarding the potential interactions of Kratom with other pharmaceuticals or with the patient's underlying medical conditions (of which, presumably, the seller was not aware), nor did the seller make any effort to ensure that the consumer discussed the use of Kratom with his medical provider prior to use. It is reasonable to assume that had Mr. Hamilton been provided with this information he would have discussed the use of Kratom with his medical provider prior to engaging in its use.

7) Because the seller ignored evidence that demonstrates at least some potential for harm with ingestion of Kratom, and because Kratom is only ever purchased for human consumption, it is reasonable to find the seller at least partially, if not wholly culpable, in Mr. Hamilton's death. The seller, having admitted to knowledge that other individuals were buying Kratom for human consumption, is negligent for not providing adequate warning labels on the product indicating the risk associated with human ingestion of Kratom including the potential for drug-to-drug interactions, disease-to-drug interactions, and toxic side effects when taken in doses higher than recommended (including respiratory depression, seizures, or death). It is reasonable to expect that such labeling would have, at minimum, prompted Mr. Hamilton to discuss the use of Kratom with his medical provider prior to consumption. It

is also reasonable to assume that such labeling would have provided Mr. Hamilton with the necessary information to avoid such drug-to-drug interactions, perhaps by discontinuing gabapentin, or drug-to-disease interactions (by being more vigilant with respect to his diabetes control with initiation of Kratom use). It is reasonable to assume that appropriate labeling (including its addiction potential) may have even deterred Mr. Hamilton from use of Kratom altogether. Given that the facts of this case demonstrate that Kratom significantly contributed to the death of Mr. Hamilton, either via direct toxicity or as a result of an interaction with prescribed gabapentin, and given that it is clear that the seller did not warn Mr. Hamilton of the danger's associated with human consumption despite seller's knowledge that other individuals had been using Kratom for this purpose, and because it is reasonable to assume that the sellers are very well aware that human consumption is what gives Kratom its value, the seller bears a significant responsibility for the death of Mr. Hamilton in this case.

Case History and Review of Stephen Hamilton's Death:

Stephen Hamilton was a 38-year-old gentleman with a past medical history significant for Type 1 Diabetes Mellitus, a severe alcohol use disorder, a severe opioid use disorder, polysubstance use, and a history of major depression who was discovered unresponsive on the floor next to his bed in March of 2017. He was pronounced dead at the scene. The Postmortem Examination Report demonstrated Pulmonary Congestion and Edema with a toxicologic report positive for mitragynine at a level of 2500 ng/mL (greater than four times the upper limit of the currently accepted toxic range for mitragynine of 20-600 ng/mL). Toxicology was also positive for gabapentin (prescribed for chronic pain) and diphenhydramine (Benadryl®). Toxicology did not demonstrate any alcohol or other substances of abuse. Cause of Death was correctly noted to be "Mitragynine Intoxication" and the Manner of Death "Accidental" by the Medical Examiner.

Past Medical History:

1) Type 1 Diabetes Mellitus Treated with an Insulin Pump at the time of death
2) Chronic Pain Syndrome due to Degenerative Disk Disease of the C-Spine
3) Chronic Eczema arms and chest
4) Hypoglycemia-associated Seizures in 2013 and 2014 (two)
5) Tobacco Use Disorder
6) Alcohol Use Disorder, Severe
7) Methamphetamine Use Disorder
8) Opioid Use Disorder, Severe
9) Polysubstance Abuse (also including cannabis, cocaine, amphetamines, and hallucinogens)
10) Major Depression, Severe, Recurrent with remission on Vortioxetine (Trintellix)

Past Surgical History:

1) C5-C6 Spinal Fusion in 1999
2) Repair of Left Knee Meniscus in 2001
3) Wisdom Tooth Extraction
4) Tonsillectomy

Prescribed Medications:

1) Insulin Pump
2) Gabapentin
3) Vortioxetine (Trintellix)

Social History/Habits: Steven was born in Lewistown, Montana. He has one younger sister who lives in California. His parents remain in Lewistown. He graduated from high school and went to college but did not graduate. He had been working in sales for many years.

Legal History:

1) DUI – Age 16

2) Battery Charge in Florida – 2013

3) DUI – 2013

4) Burglary and Criminal Mischief – 2014

5) DUI – May, 2016 (during two day relapse) – Revoked to Jail and Remained sober as far as can be determined until the time of his death.

Family History:

1) Mother - History of heart disease

2) Father – Healthy

3) Sister – History of Substance Use

4) Paternal Grandmother – Alcohol Use Disorder

5) Paternal Grandfather – Alcohol Use Disorder

6) Maternal Grandfather – Diabetes Mellitus, Unspecified Type

7) Maternal Grandmother – Diabetes Mellitus, Unspecified Type

Mr. Hamilton had an extensive history of substance use that started at age 16 with alcohol, tobacco, and cannabis. Per review of the records from his treatment episode at the Rocky Mountain Treatment Center in 2015, it appears that his substance of choice during his early years was alcohol, but he started using other substances including opioids and amphetamines at age 18. Between the age of twenty and his mid-30's he was primarily using alcohol, opioids, and tobacco but would frequently use methamphetamine when opioids were not available. His opioid(s) of choice were oxycodone (which he would occasionally inject in his later years) and fentanyl. He used heroin four times intravenously prior to his first treatment at Rocky Mountain Treatment Center in June 2015 for intravenous methamphetamine and oxycodone use. Per his own testimony in Hamilton versus MHNet, following completion of his first treatment episode at the Rocky Mountain Treatment Center (RMTC), he was hired by RMTC for a couple of weeks during which he designed their new logo and developed some of their addiction-related brochures. He eventually moved back to Lewistown, Montana after a few weeks because the sober living facility he was staying at was placing him at risk for relapse because of people using multiple substances. He contacted his probation officer who agreed that it would be best for him to move back to Lewistown. Per his own words, he remained sober from all substances for 364 days from March 1, 2015 through the End of February of 2016 when he slipped and drank alcohol for one

day. He was then sober again for 2-3 months, relapsed again on May 11, 2016, and was picked up for another DUI during that drinking episode. He spent four days in jail after which he went back to Rocky Mountain Treatment Center for 43 days on a voluntary basis. He remained abstinent again until August when he drank alcohol for one day and told his probation officer who revoked him. He spent 72 hours in jail and was once again released. By October of 2016, when he gave his Deposition for a lawsuit against his previous insurance company which had refused to pay for his first treatment at the RMTC, he was doing well on Vortioxetine (Trintellix®) and was attending treatment two days per week at Aspen Health in Lewistown, Montana. He was also attending 12-step program meetings (Alcoholics Anonymous) five days per week, Family Groups on Wednesday nights, and Celebrate Recovery on Thursday Nights.

Introduction to Kratom:

A Long History of Human Consumption of Kratom

Kratom (Mitragynina speciosa Korth) is an herb indigenous to Thailand and other countries in Southeast Asia that has been consumed by people in that part of the world for hundreds of years to stave off fatigue and to manage pain, opioid withdrawal, and cough. [2,3] In the past decade, the herb has made its way around the world via internet sales and commercial trade as an herbal alternative to opioids for pain relief, for use as a mild stimulant, and more recently as a treatment for patients with an opioid use disorder. It is sold on the internet as a "non-addictive" herbal alternative for pain control. [11,12] It is also used by many as a "legal high" and to assist with withdrawal from opioids. As a result of such human consumption, in the United States alone, Kratom has become a 1.3 Billion Dollar Industry.

A Google search for the term "Uses of Kratom other than for ingestion" yields nothing except for results discussing human consumption. A separate Google search for "Uses for Kratom" results in a myriad of web addresses all discussing the health benefits, safety, side effects, dosing, or other aspect of Kratom for Human Consumption. The American Kratom Association, "a grassroots advocacy organization with a large amount of factual data to support efforts to keep kratom legal," is the leading lobby organization and not-for-profit advocacy group for continued legalization of Kratom for human consumption. [13] As their website clearly states under the Q&A section of 'Science and Facts,' "Today, people in the U.S. are *consuming* Kratom, as they do other herbal supplements and traditional remedies." [14] In a subsequent section of the Q&A entitled 'Ways to Use Kratom,' the American Kratom Association website reports that "Kratom can be *consumed* in a number of ways. It's a natural botanical ingredient that can be used in dietary supplements, steeped as tea, taken in powder form or in capsules to safely provide energy and natural pain relief." [14] In other words, the American Kratom Association, the premiere lobbying body on behalf of American Kratom distributors, suppliers, and consumers clearly understands that the sole purpose for continued advocacy for Kratom is for human consumption. Because of this fact, and because of growing regulatory pressures from the FDA and DEA, the American Kratom Association published a "Good Manufacturing Practice (GMP) Standards for the Manufacture of Kratom Products" in 2018 which includes Marketing and Labeling guidelines [Table 1] that clearly demonstrate the intent that Kratom be used for Human Consumption. [15] While these guidelines were NOT available to the sellers at the time of Mr. Hamilton's death, the American Kratom Association website was active and clearly demonstrated that the sale of Kratom has always been intended for "human consumption." In addition, the sellers in this case were aware, as they have already disclosed in their defense, that other individuals have purchased Kratom for human consumption. As a result, the labeling of an herbal product that is clearly being sold for human consumption as 'Not for Human Consumption' is clearly an attempt by the seller to decrease their burden of liability in case the consumer develops side effects or has an adverse response to use of Kratom. Several consumer web sites make this point abundantly clear. [1] Given this information, it is unreasonable for ANY seller of kratom to claim ignorance with respect to the intended purpose of purchase for Kratom, whose ONLY monetary value is its use for "Human Consumption." As a result, the seller's claim that "recovery is barred" pursuant to Montana Code Ann. 27-1-719 which states that if a "product was unreasonably misused by the consumer" can be used as a defense in litigation is not applicable in this case because the decedent was using the Kratom exactly as it is intended to be used - for Human Consumption. Had the seller labeled the product appropriately with adequate warning and precautionary statements, there is good reason to believe that Mr. Hamilton would have sought the advice of a physician prior to

combining such use with gabapentin and with his type 1 diabetes mellitus. As for the seventh defense, in the "defendant's answer," review of the myriad of information available through the internet will clearly demonstrate that the seller's instructions represent false advertising of a product whose intent is clear at the time of purchase. Instructions on use of Kratom for a variety of indications and dosing instructions are readily available through numerous web sites and forums and the seller failed to provide such appropriate instruction, warnings, and cautionary statements to prevent litigation by labeling its product, under false pretenses, as "Not for Human Consumption." It is evident that any reasonable seller would clearly know that the purchase of Kratom by Mr. Hamilton was intended for Human Consumption as this represents the only value for the purchase of Kratom.

TABLE 1: AKA LABELING AND ADVERTISING GUIDELINES
The labels, labeling, or advertising of any kratom product should not bear any disease claims (i.e., claims regarding the treatment, cure, prevention, or mitigation of disease) or unauthorized health claims.
The labels, labeling, or advertising of any kratom product should not bear any structure/function claims.
The labels, labeling, or advertising of any kratom product should not reference any research or clinical data.
Each finished product label must include a batch or lot number.
Each finished product should be labeled to disclose the mitragynine and 7-OH alkaloid content of the product.
Each finished product label must advise consumers to consult with a physician for dosing information relative to alkaloid values.
No kratom products may be sold to individuals under the age of 18.
The label should bear a statement that pregnant women should not use kratom products during pregnancy.
All labels, labeling, or advertising should include the following statement: "This product is not intended to diagnose, treat, cure, or prevent any disease or condition."

Current Science of Kratom

Kratom is known to contain several active phytochemicals, but the chemical entity's mitragynine (the plant's primary alkaloid) and 7-hydroxy mitragynine (a minor alkaloid) are widely regarded to be the primary alkaloids that produce most the plant's psychoactive effects with additional contributions from other phytochemicals, including mitraphylline. [2,3,16,17] When ingested orally, the bioavailability of mitragynine is estimated in the laboratory to be approximately 3.03% with an onset of action of approximately 5-10 minutes. [18] The half-life of mitragynine is not known with certainty but its effects appear to last several hours consistent with the initiation of withdrawal symptoms within 12-24 hours for most individuals who use Kratom. [18, 19] At low doses, mitragynine has stimulant effects, but at high doses, mitragynine behaves like an opioid and has been shown to have partial agonist activity at the Mu and Kappa-opioid receptors. [18, 20] A recent systematic review has also determined that there is a "lack of available evidence in support of Mitragynina speciosa for any clinical indication." [2] Mitragynine, the primary active component of kratom, is currently being investigated as a potential analgesic with a diminished risk of respiratory depression in overdose compared to traditional opioid analgesics. [20,21] At the present time, however, the clinical properties of mitragynine and its potential for development as a therapeutic agent are only in the early stages of investigation.

As noted previously, the primary psychoactive chemical components of Kratom (a botanical) are mitragynine and 7-Hydroxy Mitragynine. Mitragynine is known to possess partial Mu-Opioid agonist activity and Kappa receptor antagonist activity similar to the FDA-Approved pharmaceutical drug, buprenorphine (marketed by various names and formulations and most commonly known as Suboxone® by the lay press). Buprenorphine has partial Mu-Opioid agonist activity and Kappa antagonist activity

similar to Mitragynine. Unlike Buprenorphine, however, mitragynine may also possesses Delta Opioid Receptor agonist activity and mild stimulant properties whose biochemical nature has not been clearly delineated (though the stimulant properties may be on par with caffeine given the botanical relationship of Kratom to the Coffee plant). 7-Hydroxy Mitragynine, which tends to be present in lower concentrations than mitragynine in Kratom (approximately 2%), is a full Mu Opioid Receptor agonist with Kappa Receptor activity that has been shown to be 13 times more potent than morphine and 46 times more potent than mitragynine. [2, 22] 7-hydroxy Mitragynine is now thought to be the primary alkaloid contributing to the pain-relieving properties of Kratom. [22] Given that 7-hydroxy mitragynine is a potent full mu-opioid receptor agonist, unlike mitragynine, at higher doses, respiratory depression is likely to be of much greater concern than with mitragynine.

Unadulterated Kratom, like buprenorphine, is most likely safe for consumption at "usual" doses of administration AND when not used in combination with other sedative/hypnotic/anxiolytic substances (including, but not limited to benzodiazepines, meprobamate, barbiturates, other opioid substances, gabapentin, or pregabalin), but can contribute to fatalities in combination with one (or more) of these agents and very likely when taken in an amount greater than the "usual" dose. [2, 12, 23, 24, 25] In other words, while Kratom is not known to possess toxicity on par with other pure Mu-opioid receptor agonists (such as heroin, oxycodone, morphine, etc.), Kratom appears to possess toxicity on par with that of the pharmaceutical agent buprenorphine (a partial mu-opioid agonist that has also been linked to a number of deaths in combination with other agents and much less commonly, on its own at higher doses). The FDA recently published a computer modelling study that demonstrates what laboratory studies have already shown, that the active chemicals in Kratom (Mitragynine and 7-hydroxy mitragynine) function as mu-opioid receptor agonists, which is why individuals have touted the benefits of Kratom to prevent opioid withdrawal and assist with cravings. [4] At high doses, Kratom (and more specifically its active components mitragynine and 7-hydroxy mitragynine) have also been shown to increase the risk of a fatal heart arrhythmia, through prolongation of the QT-Interval, known as Torsade De Pointe (a similar effect that is seen with methadone and which is possible with any opioid analgesic at a high enough dose).[5] Kratom has also been linked to seizures and liver toxicity. [11,26,27,28] The CDC has published reports that demonstrate such morbidity and mortality associated with use of Kratom that was well known prior to initiation of sales of Kratom to Mr. Hamilton. [6] As noted previously, Kratom has been associated with at least 44 deaths in the United States (most in combination with another sedative/hypnotic/anxiolytic agent, alcohol, psychotropic medications, or another opioid) and that buprenorphine (a prescription opioid with similar pharmacology to mitragynine) has been associated with similar deaths. [4]

As noted previously, the internet is ripe with sites and articles that proclaim the pain relieving and stimulant properties of kratom while downplaying its adverse side effects and addiction potential. Numerous case series and reports, however, have described the addiction potential of kratom, both in herbal form and as an extract. [16,17,19,28-32] The oldest of these published articles dates back to 1975 with an early description of Kratom addiction in the Thai population. [16] In fact, rat models, (which are typically used to test the abuse potential of a substance) demonstrate that rats were able to distinguish mitragynine (the primary component of Kratom) as well as morphine in this study. [33] In this study, mitragynine substituted completely for morphine in the rats. In a more recent study carried out to determine the risk of suicide among illicit drug users in Thailand, the investigators report that the

primary drug of abuse in their study was kratom (illegal in Thailand since 1943) which was used by 59% of the 537 respondents who admitted to illicit drug use, followed by methamphetamine (24%). [17]

More recently several case series and reports of kratom toxicity have started to surface in the United States and Europe. In one such report, a male patient abusing and addicted to hydromorphone attempted to use kratom to prevent withdrawal and was admitted to the hospital after he mixed the kratom with modafinil (a stimulant) and suffered a generalized tonic-clonic (grand mal) seizure. [11] In a separate case series from Sweden, investigators report on nine cases of krypton intoxication and death; krypton is an herbal preparation of dried, crushed kratom leaves mixed with another mu-opioid receptor agonist, O-desmethyltramadol. [12] In at least three case series the abuse potential, toxicity, and withdrawal symptoms associated with kratom use have also been described. [16,17,19,28-32] Three additional case reports have also demonstrated the potentially fatal effects of kratom without the addition of other mu-opioid agonists when taken in combination with other sedative/hypnotic/anxiolytic agents. [2,12,23,24,25]

Kratom is not currently scheduled by the Drug Enforcement Agency (DEA) but is listed on its "Drugs and Chemicals of Concern" list. In 2016, the FDA/DEA attempted to list Kratom as a schedule 1 narcotic based on increasing reports of toxicity associated with use of Kratom as noted above. The DEA's attempt failed due to the strength of the grass roots advocacy efforts of the American Kratom Association, multiple scientists who believe that the constituents of Kratom may provide a new pharmaceutical for management of pain and opioid use disorder, and individual proponents of Kratom use which resulted in a Bipartisan coalition in Congress writing a letter to the FDA to postpone its action and to obtain additional information, clinical studies, and to hold a public listening session. The FDA has yet to provide a final ruling on the status of Kratom. Several States and municipalities have banned the production, distribution, sale, and/or consumption of Kratom within their borders because of concerns regarding the safety profile of Kratom including Alabama, Arkansas, Indiana, Rhode Island, Vermont, Wisconsin, and Washington, D.C. Kratom is also banned in numerous municipalities including Sarasota County in Florida, San Diego in California, and Jerseyville in Illinois. Numerous states also have pending legislation to ban Kratom including Illinois, Mississippi, New York, New Jersey, and West Virginia. In addition, Kratom has been banned for safety concerns in the following countries: Australia, Denmark, Finland, Israel, Lithuania, Malaysia, Myanmar, Poland, Romania, South Korea, Sweden, Thailand, and the United Kingdom. [8,9]

REVIEW OF FACTS:

It is important to note at this point that during his deposition on October 7, 2016 in the case of Stephen Hamilton versus MHNet, his attorney, Torger Oaas, asked Mr. Hamilton (page 171) if he had used "Narcotics. Have you used any?" Mr. Hamilton responded, "I have not used any narcotics since March 2nd or 1st of 2015." He admitted in that deposition to taking numerous drug tests for his probation officer all of which were negative for the substances tested (it should be noted at this time that mitragynine, the primary active component of Kratom is not detected on a routine drug test and therefore his tests would not demonstrate its presence). Mr. Hamilton admitted in the deposition that he was tested for opioids, benzodiazepines, THC, LSD, Methadone, and methamphetamine. During this period of time, however, he did admit to alcohol use (as noted above) but drug tests consistently demonstrated that he had maintained abstinence from all substances of abuse. At no point during the deposition was he asked about herbal products (Kratom) or supplements, nor did he volunteer such information. At this point, it should also be noted that in her Second Declaration Witness Statement for this case, Stephanie Cataraha, Steven Hamilton's sister, stated that she had discovered sixteen (16) sales of Kratom to Stephen Hamilton from Elemental Prism d/b/a Herb Stomp between October 17, 2015 and March 20, 2017. As noted previously, the active components of Kratom (Mitragynine and 7-hydroxy-mitragynine) do not give a positive result on a routine urine drug test such that his urine drug tests would be negative for all substances tested. In addition, Kratom was not, and as of the writing of this expert testimony, is not illegal or banned by the federal government, the State of Oregon, or the State of Montana, and would have been legal to purchase online. Despite Kratom NOT being approved for ANY medical indication in this (or any other) country, as noted previously, a quick review of a search for "Kratom" or "uses for Kratom" on Google demonstrates that it is marketed by many sellers as a "non-opioid, non-addictive, alternative for pain" and as a potential treatment option for opioid withdrawal and addiction. As noted previously, its only monetary value is its use "for human consumption." It is clear from his own deposition, that Mr. Hamilton did not believe, and most likely did not realize, that Kratom, which he had apparently been taking since October of 2015, had opioid-like properties or an addiction potential. It is also clear from the packaging of Kratom from Herb Stomp [see photograph of package] that there was no label on the package indicating potential risks, benefits, or adverse effects of Kratom ingestion. Mr. Hamilton, like many other individuals who use Kratom (and other herbals) every day, was likely unaware of the fact that an herb could interact with his prescribed medications or have severe adverse effects such as addiction, overdose, or death. Given that Mr. Hamilton had been actively engaged in addiction treatment since October of 2016 and was working hard to maintain his sobriety and get his life back on track, it is reasonable to assume that had he known about Kratom's potential for addiction, its drug-to-drug interaction potential with gabapentin, or Kratom's opioid effects with resulting risk of overdose and death, he would have, at minimum, discussed its use with his treatment providers or forgone its use altogether.

It should also be noted that Mr. Hamilton had also experienced numerous skin and soft tissue infections resulting from his diabetes mellitus. From Late 2016 through 2017 prior to his death, Mr. Hamilton underwent several surgeries related to diabetic wounds and infection of an intravenous site. He was in a great deal of pain but continued to avoid use of opioid analgesics because he did not want to relapse. Instead, it appears that Mr. Hamilton, believing that Kratom was a "non-addictive and natural" substitute for opioid analgesics, and likely believing that it is a safe herbal product given the information available on most websites regarding its risks, utilized the herbal Kratom to help relieve his

pain so that he did not have to use prescription opioid analgesics which had caused him so much suffering in the form of addiction. Because the Kratom he used was not adequately labeled to instruct individuals on the potential risks and adverse effects of Kratom or the potential of Kratom to interact with pharmaceutical medications, Mr. Hamilton continued to use Kratom and likely developed a tolerance to some of its effects leading him to have to continuously escalate the dose. Given that he was not aware of the risk of overdose and death with Kratom, especially since most Kratom distributors downplay the significance of this risk, and given that gabapentin has been shown to potentiate the effects of opioids thus increasing the risk of overdose and death with any opioid, Mr. Hamilton was likely unaware of the risk associated with increased doses of Kratom and eventually succumbed to acute mitragynine (Kratom) intoxication resulting in death either from a fatal arrhythmia (as noted previously, mitragynine has been shown to increase the risk of Torsade's de Pointe) or respiratory failure (a direct effect of its opioid-like properties). It is important to note that the level of mitragynine in Mr. Hamilton's blood at the time of death (2500 ng/mL) is 4 times greater than the currently accepted toxic range of mitragynine in humans (50-600 ng/mL). It is also important to note that gabapentin (when given alone) has never been associated with mortality. Individuals have taken very high doses of gabapentin by itself without a notable risk of mortality. In fact, gabapentin, when taken alone, has not been found to have a Lethal Dose 50 (the dose of ingestion at which 50% of those who take that dose will die). Unfortunately, more recent data does suggest that the use of gabapentin with opioid analgesics potentiates the risk of overdose and death from opioids, [34] a fact that Mr. Hamilton's treating physicians could have warned him about had Mr. Hamilton been advised (via an appropriate package label) of the risk of potential drug interactions. All other herbal remedies sold over-the-counter (Saint John's Wort, Saw Palmetto, Kava Kava, Valerian Root, etc.) have a label telling consumers that they should discuss use of the herbal with their healthcare provider prior to initiation of use due to risks associated with drug-to-drug interactions or drug-disease interactions. It is reasonable to assume that had the Kratom that Mr. Hamilton received been labeled appropriately, he would have sought the advice of his healthcare professional prior to use of Kratom.

SUMMARY OF EXPERT TESTIMONY:

1) The facts of this case show that despite stating on their website that the product (Kratom) is "Not Intended for Human Consumption," the seller was aware, or at least any reasonable seller would have been aware, that the sale of Kratom (in any of its forms) was being utilized by the purchaser for human consumption, and that by stating that the product is "not for human consumption," the seller was only trying to avoid litigation if an individual (such as Mr. Hamilton) were to have an adverse reaction from ingestion. The facts of the case demonstrate that the seller had NOT labeled the package itself as "not for human consumption." The seller's attempt, therefore, to mitigate litigation by stating on its website that Kratom, a product the seller is very well aware is being used solely for human consumption, as "not for human consumption," is not reasonably protected by Montana statute as stated in the seller's defense (Page 3, Third Defense).

2) The facts of this case demonstrate that Kratom is not approved for use for ANY medical condition in the United States of America and that it is associated with certain known risks and adverse side effects including the potential for seizures, liver toxicity, addiction, withdrawal, overdose, and death.

3) The facts show that Kratom is most likely safe for consumption at "usual" doses of administration AND when not used in combination with other sedative/hypnotic/anxiolytic substances (including, but not limited to benzodiazepines, meprobamate, barbiturates, other opioid substances, gabapentin, or pregabalin), but can contribute to fatalities in combination with one (or more) of these agents or when taken in an amount greater than the "usual" dose. There have been at least 44 deaths linked with ingestion of Kratom.

4) The facts demonstrate that as a result of the increasing number of calls to poison control and the potential for morbidity and mortality associated with inappropriate labeling and use of Kratom, the Food and Drug Administration (FDA) attempted to ban the substance in 2016 by using its emergency powers to change the Federal Drug Enforcement Administration (DEA) schedule of Kratom to a Schedule 1 (illegal) Controlled Substance. The FDA attempt ban Kratom was halted by a grass roots effort from the Kratom industry and individuals who use kratom but Kratom has been banned in several states and jurisdictions in the United States and is illegal in several countries, including its indigenous countries of Thailand and Malaysia.

5) The facts show that Mr. Hamilton suffered from a severe opioid use disorder, an alcohol use disorder, Type 1 Diabetes Mellitus, polysubstance use, and Major Depression but also demonstrate that he was very involved in treatment for his addiction prior to his death and was working hard to get his life back in order. The facts demonstrate that he was using Kratom as an herbal remedy to help with pain from multiple wounds associated with his diabetes. The facts demonstrate that the kratom package was not labeled with warnings to discuss the use of Kratom with his healthcare provider prior to use. Had the package been labeled with appropriate warnings, it is reasonable to assume that Mr. Hamilton, who was working hard in his recovery from substance use would have sought the advice of his healthcare provider prior to use of kratom or would have avoided use of Kratom altogether.

6) The facts of this case show that Mr. Hamilton's use of Kratom significantly contributed, if not actually caused, his death. Mr. Hamilton's toxicology report after death demonstrated a mitragynine level (the primary psychoactive component of Kratom) that was significantly higher (2500 ng/ml) than levels reported in other cases where Kratom was considered contributory to the cause of death (20-600 ng/ml). His toxicology report did not demonstrate any other substances except gabapentin (which he had been prescribed for pain) and Diphenhydramine (Benadryl®), neither of which could have accounted for his death on their own.

7) Given that the facts of this case demonstrate that Kratom significantly contributed to the death of Mr. Hamilton, either via direct toxicity or as a result of an interaction with prescribed gabapentin, and given that it is clear that the seller did not appropriately warn Mr. Hamilton of the danger's associated with human consumption despite seller's knowledge that other individuals had been using Kratom for this purpose, and because it is reasonable to assume that the sellers are very well aware that human consumption is what gives Kratom its value, the seller bears a significant responsibility for the death of Mr. Hamilton in this case.

Signature:

Date:

October 19, 2018

David Galbis-Reig, M.D., DFASAM

APPENDIX A – REFERENCE LIST

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